K081693

FEB 23 2009

510(k) Summary

Date Prepared:	August 15, 2008
Submitter's Name:	Calgary Scientific, Inc.
Submitter's Address:	1210 20th Ave. SE, Calgary, Alberta, Canada T2G 1M8
Submitter's Phone:	403.270.7159
Submitter's Fax:	403.270 2771
Contact:	Pierre Lemire, President & Chief Operations Officer
Proprietary Name:	ResolutionMD™ 2.1
Common Name:	Software PACS
Classification:	892.2050 Picture archiving and communications system, Product Code LLZ, (Class II)
Substantially Equivalent to:	Tradename: Vitrea, Version 4.0 and Vital Connect 4.1 Manufacturer: Vital Images, Inc. 510(k) Number: K071331 and K071362

Device Description:

The ResolutionMD™ 2.1 is a software based Picture Archiving and Communication System (PACS) used with general purpose computing hardware for the display and 3D visualization of medical image data. It provides for communication, storage, processing, rendering, and display of DICOM 3.0 compliant image data derived from various sources including CT and MRI. The ResolutionMD™ software takes advantage of dedicated graphics hardware to speed the creation 3D rendered images.

The ResolutionMD™ 2.1 is available in a Microsoft Windows version, a Microsoft .NET software development kit version (SDK), a Linux Web server version and in a Macintosh OS version. All versions offer similar functionality. Available functions include DICOM communication, display of 2D images in original planes, computation and display of rendered 3D images and maximal intensity projection (MIP) and multiplanar reconstruction images (MIP/MPR), 2D and 3D image measurements, calcium scoring, and coronary artery analysis. The user controls these functions with a system of interactive menus and tools.

A hazard analysis has been conducted and the level of concern has been classified as minor. The ResolutionMD™ 2.1 software will be extensively tested on supported platforms by members of the development and quality control team prior to beta testing. Beta testing by trained cardiology professionals and potential customers will be completed prior to product release. The release version of the software will be required to pass all tests considered critical in terms of patient safety and demonstrate an overall acceptable performance for release as determined by the predefined release criteria.

Substantial Equivalence Comparisons to Predicate Device:

Feature	ResolutionMD™	Vital Vitrea2™	Vital Connect 4.1
Computer Platform	Windows OS, Microsoft .NET SDK, Linux OS, or Mac OS	Windows OS	Windows OS
DICOM compliance	DICOM 3.0	same	same
LAN, WAN and Web access	Server with PC Client access via the Internet, LAN or WAN	N/A	same
2D Imaging	2D image viewer with interactive user controls	same	same
3D Imaging	3D volume rendering with interactive controls	same	same
Measurement	2D measurement tools	same	same
Maximum Intensity Projection (MIP)	MIP with interactive controls and clipping planes	same	same
Multiplanar Reformatting (MPR)	MPR with oblique slicing and variable thickness slabbing	same	same
Segmentation	Manual, semi-automatic and automatic delineation of an sub-region within an image	same	same
Prescription Use	Yes	same	same
Intended Users	Trained professionals	same	same
Calcium Score	Agatston and volumetric scores	same	same
Artery detection	Automated and manual centerline detection	same	same
Curved multi-planar reconstruction	Curved MPR of artery centerline with cross-sectional images	same	same
Reporting	Report summary generation from Cardiac analysis	same	same

Intended Use:

The ResolutionMD™ 2.1 is a software-based Picture Archiving and Communication System (PACS) used with general purpose computing hardware for the display and 3D visualization of medical image data. It provides for communication, storage, reformatting, rendering, and display of DICOM 3.0 compliant image data derived from various sources including CT and MRI.

The ResolutionMD™ 2.1 device incorporates a Calcium Scoring module which is used to identify and quantify calcified plaque within the coronary arteries. This protocol is performed on non-contrast enhanced cardiac CT data sets. It also includes the Coronary Artery Analysis protocol which is used to visually identify and measure stenoses in the coronary arteries. This protocol is performed on contrast-enhanced cardiac CTA data sets.

The ResolutionMD™ 2.1 software is intended for use as a diagnostic, review, and analysis tool by trained professionals such as physicians, technologists, and nurses. When interpreted by a trained physician, reviewed images may be used as an element for diagnosis. It is the user's responsibility to ensure that the software is installed on appropriate hardware and that image quality is suitable for the clinical application. Calgary Scientific recommends that users of the ResolutionMD™ 2.1 software consult the appropriate American College of Radiology Practice Guidelines pertaining to the anatomy and pathology being studied.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Pierre Lemire
President & Chief Technology Officer
Calgary Scientific, Inc.
Suite 208, 1210 20th Avenue SE
Calgary, AB T2G 1MB
CANADA

FEB 2 3 2009

Re: K082693
Trade/Device Name: ResolutionMD™ 2.1
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 6, 2009
Received: February 10, 2009

Dear Mr. Lemire:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Exhibit 1 – Revised Indications for Use statement

Indications for Use

Applicant: Calgary Scientific, Inc., Suite 208 – 1210 20th Ave. SE,
Calgary, Alberta, CANADA T2G 1M8

510(k) Number (if known): K082693

Device Name: ResolutionMD™ 2.1

Indications for Use:

The ResolutionMD™ 2.1 is a software-based Picture Archiving and Communication System (PACS) used with general purpose computing hardware for the display and 3D visualization of medical image data. It provides for communication, storage, reformatting, rendering, and display of DICOM 3.0 compliant image data derived from various sources including CT and MRI.

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082693

Concurrence of CDRH, Office of Device Evaluation (ODE)